

IN THE ABSTRACT:

A substitute abstract making explicit the points discussed below is provided.

IN THE CLAIMS:

1. A method for enhancing compound/drug penetration into hair follicles on body areas of animals and humans, comprising the steps of:
 - a. simultaneously applying topically said compound/drug and a swellable composition to said body areas with an intact stratum corneum;
 - b. allowing said composition to penetrate into said hair follicles; and
 - c. volume swelling said swellable composition, wherein internal forces are generated by said swellable composition at said hair follicles during and after said volume swelling of said composition to prevent collapse of said follicle during release of said compound/drug.

REMARKS

Claims 1, 2, 10, 11-12, 14-15, 19 and 20 stand rejected under 35 USC 102(b) as being anticipated by Suzuki et al. (U.S. 4,292,299). Applicant respectfully disagrees. Applicant has also modified the claims to more explicitly describe the present invention and differentiate it from the prior art.

Examiner describes Suzuki as being applicable to "wet mucus surface of a mucous membrane and **skin** . . ." (1/28/02, page 1). This characterization of Suzuki's applicability is somewhat misleading, in that examiner apparently interprets this to mean all layers of skin. Suzuki only applies to "wet" layers, such as mucous membranes in body cavities or exposed interior layers of the skin. Examiner, in Advisory Action dated June 18, 2002, points out that "the wet mucous surface can be part of the skin containing hair follicles". Examiner points to col. 10, lines 65-69 of Suzuki as support for this argument. However, that line specifically limits application to "the **wet mucous surface resulting from operation, cut or wound.**" This

specifically excludes intact skin where there is no exposed wet surface from a cut or wound. While it is claimed that Suzuki can be applied to skin, it is limited to interior layers of skin that can be exposed by cuts or wounds. The fact that Suzuki limits applicability on the skin to cuts or wounds implies that the invention is not suitable for intact layers of skin. There is no mention of the ability to use Suzuki on intact skin, or skin with an intact stratum corneum. Such outer layers of skin cannot be characterized as "wet" as is required in Suzuki. Intact skin has as an outer layer, the stratum corneum, which consists of a layer of dead cells that repel moisture. It could not be considered a wet surface. Because the stratum corneum repels moisture, it presents difficulties in topically administering certain drugs to the interior of the body. Suzuki does not purport to be able to penetrate the stratum corneum, nor is there any suggestion that penetration of the stratum corneum could be a potential use.

Additionally, using the present invention on a cut or wound, as would be required by Suzuki for topical use, would preclude the need to penetrate hair follicles, because any barrier function created by the stratum corneum would have been neutralized due to the wound.

Also, another important distinction occurs by the fact that the present invention provides a method to penetrate the barrier that is the skin's outer layer. This is in contrast to Suzuki, which provides a means for timed release of drugs/compounds, and provides no means for penetrating the outer layer of skin. Hence the restriction of Suzuki to wet mucous surfaces. This is an important distinction, because if the method described Suzuki is performed on tissue with a barrier such as the stratum corneum, the compound would be slowly released, but that would be useless because no method or means is disclosed in Suzuki for penetrating such a barrier. Suzuki's inefficacy for use on intact skin was pointed out in our reply of April 26, 2002, page 2, par. 5.

Claim 1 has been amended to more accurately differentiate the present invention from Suzuki and to make explicit those differences that are described above.

Examiner rejects claims 1, 2, 4-5 and 10-20 under 35 USC 103(a) as being unpatentable over Suzuki in view of Schaefer. Examiner contends that it would have been obvious to one having skill in the art to combine the teachings of Suzuki and Schaefer.

As examiner contends, combining the above two inventions appears to incorporate many of the aspects of the present invention. However, these inventions have very different goals. Suzuki purports to enhance delivery of a drug to a wet mucous surface through adhesion of the

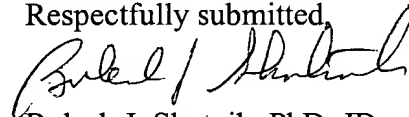
drug carrier to such surface. Schaefer has the very different goal of increasing penetration through the hair follicles of skin. One skilled in the art would not be motivated to use an adhesive composition to further enhance drug penetration. Indeed, the use of an adhesive substance from Suzuki would be detrimental to a penetration means such as in Schaefer, because by nature an adhesive substance would restrict movement of particles. The present invention relies on the ability of the microparticles to freely travel into hair follicles, and a composition that restricts such movement would be contrary to this goal. Because the above two inventions attempt to solve very different problems, there is no direct reason for combining these inventions without hindsight after seeing the present invention. For the above reasons, the present invention is not obvious over Suzuki in view of Schaefer.

With these changes and remarks it is believed that the disclosure is now in condition for allowance. Reconsideration is respectfully requested. An early and favorable response is earnestly solicited. Thank you.

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